FDA 510(k) Premarket Notification

K222757 Clarus Viewer

CLEARED

Feb 24, 2023
165 days to decision

K222757 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k222757/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 12, 2022
Decision date	Feb 24, 2023
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Clarus Viewer Corporation**
Location	Huntsville, AL, US
Contact	Steve Thomas
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Kapstone Medical, LLC**
Contact	Carolyn Guthrie

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov